

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P.,
and RHODES TECHNOLOGIES,

Plaintiffs,

v.

COLLEGIUM PHARMACEUTICAL, INC.,

Defendant.

C.A. No. _____

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, “Purdue” or “Plaintiffs”), for their Complaint herein, aver as follows. The present case is related to consolidated Civil Action Nos. 15-13624 and 15-13099, pending before Judge Saylor in this Court, because it involves the same parties, same Collegium NDA No. 208090, and same accused product (*see infra* ¶¶ 12-15; C.A. No. 15-13624, Compl. ¶¶ 27-30; C.A. No. 15-13099, Compl. ¶¶ 34-37), and will therefore involve common questions of fact and law.

SUMMARY OF CLAIMS PRESENTED AND RELIEF SOUGHT

1. Plaintiffs seek judgment that Defendant Collegium Pharmaceutical, Inc. (“Collegium”) has infringed U.S. Patent No. 9,073,933 (“the ‘933 patent”), which issued on July 7, 2015. At the time the related cases were filed, Collegium had not yet given notice under 21 U.S.C. § 355(b)(3) that it challenges the ‘933 patent (*see infra* ¶ 15). The ‘933 patent relates to an improved active pharmaceutical ingredient (“API”) and processes for making such API. The

‘933 patent is listed in the FDA’s “Orange Book” as covering Purdue’s OxyContin[®], an extended-release pain medication. Collegium has infringed the ‘933 patent under 35 U.S.C. § 271(e)(2)(A) by filing New Drug Application (“NDA”) No. 208090 on its proposed XTAMPZA ER[™] product.

NATURE OF THE ACTION

2. This is an action for relief from patent infringement, arising under the patent laws of the United States, Title 35, United States Code.

THE PARTIES: PLAINTIFFS

3. Plaintiff Purdue Pharma L.P. (“Purdue Pharma”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner of the ‘933 patent, identified in paragraph 11 below. Purdue Pharma is also the holder of NDA No. 022272 for the extended-release oxycodone pain-relief medication OxyContin[®] and is involved in the sale of OxyContin[®] in the United States.

4. Plaintiff The P.F. Laboratories, Inc. (“P.F. Labs”) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner of the ‘933 patent, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin[®].

5. Plaintiff Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the ‘933 patent, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin[®].

6. Plaintiff Rhodes Technologies (“Rhodes”) is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the ‘933 patent, and is involved in the manufacture of the API used in the extended-release oxycodone pain-relief medication under the brand name OxyContin®.

THE PARTIES: DEFENDANT

7. Collegium is currently a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Collegium because Collegium has its principal place of business in this Judicial District. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE ‘933 PATENT

10. The U.S. Food and Drug Administration’s (“FDA”) *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) identifies drug products that have been approved by the FDA under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). The Orange Book also provides a listing of patents that cover a given drug product.

11. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title, and interest in the ‘933 patent entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE,”

including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin[®], which is the subject of approved NDA No. 022272. A copy of the '933 patent is attached hereto as Exhibit A, which was duly and legally issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANT'S NDA

12. Upon information and belief, Collegium submitted NDA No. 208090 to the FDA, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of XTAMPZA ER[™] oxycodone extended release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg ("the proposed Collegium Product") before the expiration of the '933 patent. The proposed Collegium Product is in the late stages of development and Collegium is actively preparing to make and sell that product if and when it is approved by the FDA.

13. Upon information and belief, the proposed Collegium Product does not literally include oxycodone hydrochloride salt, but does include a different salt, oxycodone myristate, which is equivalent to oxycodone hydrochloride for purposes of the inventions claimed in the '933 patent.

14. Upon information and belief, Collegium's NDA No. 208090 contains a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(iv) alleging that the '933 patent, listed in the FDA's Orange Book as covering the drug OxyContin[®], which is the subject of approved NDA No. 022272, is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of [the proposed Collegium Product]."

15. In a letter dated September 23, 2015 addressed to Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes, and received on September 24, 2015,

Collegium provided “Notice” with respect to the proposed Collegium Product and the ‘933 patent under 21 U.S.C. § 355(b)(3).

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE ‘933 PATENT

16. Collegium’s submission of its NDA was an act of infringement of the ‘933 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

17. Upon information and belief, the proposed Collegium Product is covered by one or more claims of the ‘933 patent.

18. Upon information and belief, Collegium’s commercial manufacture, use, sale, offer for sale, and/or importation of the proposed Collegium Product would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ‘933 patent.

19. The acts of infringement by Collegium set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

ON PLAINTIFFS’ FIRST CLAIM FOR RELIEF,
AS SET FORTH IN THE COMPLAINT:

A. Adjudging that Collegium has infringed U.S. Patent No. 9,073,933 (“‘933 patent”), and that the commercial sale, offer for sale, use, manufacture, and/or importation of the proposed Collegium Product described in NDA No. 208090 would infringe, induce infringement of, and/or contribute to the infringement of the ‘933 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 208090, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the date of expiration of the ‘933 patent plus

any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Collegium, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '933 patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: November 6, 2015

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